EMV3.1

Self-Monitoring Blood Glucose System

User's Manual

Please read this User's Manual thoroughly before using your blood glucose meter.

Dear EMV3.1 SMBG System Owner,

Thank you for using the **EMV3.1** Self-Monitoring Blood Glucose (SMBG) System. We designed this system to be dependable, easy-to-use, compact, lightweight and portable to help you monitor your blood glucose on a regular basis.

Please read this manual thoroughly before you begin testing. This manual provides you and your diabetes care team with important information and step-by-step direction to use the **EMV3.1** Self-Monitoring Blood Glucose System. To start testing quickly, you can also refer to the Quick Reference Guide.

Thanks again for choosing the **EMV3.1** SMBG.

Intended Use

The **EMV3.1 Self Monitoring Blood Glucose Test System** is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, or forearm. Testing is done outside the body (In Vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by a single patient with diabetes and should not be shared, as an aid to monitor the effectiveness of diabetes control. The system includes the speaking function but is not intended to be operated by visually impaired users. The system is not to be used on neonates, nor for the diagnosis of, or screening for diabetes mellitus. Alternative site testing can be only used during steady-state blood glucose conditions.

Important Safety Instructions

Lancets and meters are for single use only. A new, sterile lancet should be used one time you perform a test. The lancing device, lancets and meter are NOT to be shared between users or other family members. Do NOT use on multiple individuals. Sharing a lancing device and lancets may transmit blood borne pathogens, such as viral hepatitis.

All parts of the kit are considered biohazardous and may transmit infection, even if you have performed cleaning and disinfection. Wash hands thoroughly with soap and water after handling the meter or lancing device.

For further information, please see: *"FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication"* (2010) http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.

"CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Blood borne Pathogens" (2010) http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

Standard Accessories

The **EMV3.1** Blood Glucose meter and accessories are working together to measure the amount of glucose in your blood. The system includes:

- **EMV3.1 Blood Glucose Meter**
- **Alkaline Battery (2 ct)**
- **EMV3.1 Blood Glucose Test Strips (10 pcs)**
- **Test Strip Instructions**
- **Lancets (10 pcs)**
- **Lancing device**
- **AST Lancing Device Cap**
- **User's Manual**
- **Quick Reference Guide**
- **Self-Test Log Book**
- **EMV3.1 Level 2 Control Solution**
- **Control Solution Instructions**
- **Carrying Case**

Optional Accessories

- **EMV3.1 Level 3 Control Solution**

Note:
1. **EMV3.1 Level 2 Control Solution is included with the system.**
2. **EMV3.1 Level 3 Control Solution are available. For purchase, please call the Customer Care Service toll-free at 866-994-3345 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM).**

Why is it so important to test blood glucose regularly?

Testing your blood glucose regularly can make a big difference in how you manage your diabetes every day. We have made this SMBG system as simple as possible to help you use it regularly. Your meter is easy to use, and you can adjust the lancing device for your comfort.

Do you need help?

If you have questions or need assistance, please call the Customer Care Service toll-free at 866-994-3345 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM). During non-service hours, please contact your healthcare professional.

Note:
Although the EMV3.1 SMBG System is easy to use, you may need to consult with your healthcare professional (this may be your doctor, pharmacist or diabetes nurse educator) for instructions on how to use the system. Only the correct use of the system will ensure accurate results.

Important Information about Your New Meter

- **EMV3.1** blood glucose meter is designed and approved for testing in fresh capillary whole blood samples from your fingertip, palm or forearm. The meter is for in vitro diagnostic use ONLY (for testing outside the body). It should not be used to diagnose or screen for diabetes.
- **EMV3.1** blood glucose meter can only be used with **EMV3.1** Blood Glucose Test Strips. Other test strips will give inaccurate results.
- Testing is not valid for neonatal blood specimens.
- Do not disassemble the meter as this may cause damage to the components resulting in incorrect readings. Disassembling the meter will also void the warranty.
- Always keep the meter clean and store it in a safe place. Protect the meter from direct sunlight to ensure a longer lifespan.
- You should not store the meter and test strips in a car, bathroom, or refrigerator. The store condition should be at 36-86°F (2-30°C) and 40-85% RH.
- Keep the meter, test strips and lancing device away from children and pets.
- This meter should not be used on the critically ill.
- Incorrect results may occur when performing the test. If you believe you are not feeling well, please contact your healthcare professional.
- Remove batteries if the meter will not be used for one month or more.

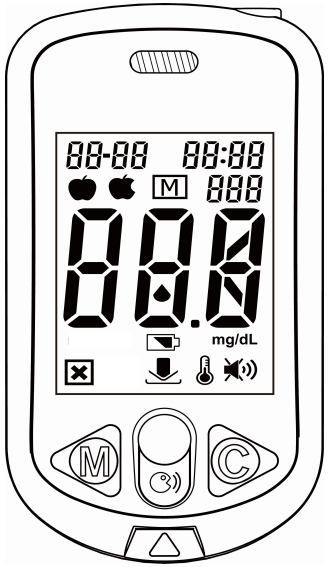
Note:

- Consult with your healthcare professional before testing on your fingertip, palm or forearm.
- Do not touch the strips with wet hands.
- Do not use expired strips (the expiration date is shown on the bottle.)
- Do not bend, cut or twist the strips.
- Altitude up to 10,000 feet above sea level has no effect on readings.
- It should not be used to diagnose or screen for diabetes.

Health-Related Information

- If you are experiencing dehydration, frequent urination, low blood pressure, shock or hyperosmolar hyperglycemic nonketotic coma (HHNKC), you may get a test result that is lower than what your blood glucose really is. If you think you are dehydrated, call your healthcare professional right away.
- If you have followed the steps in the user's manual, but still have symptoms that don't seem to match your test results, contact your Healthcare Professional or physician immediately. If you have questions regarding the use of the meter, please call the Customer Care Service toll-free at 866-994-3345 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM). During non-service hours, please contact your healthcare professional.
- Please read your test strip instructions carefully for additional health-related information.

Explanation of Meter Symbols



88-88	Date		Before Meal
88:88	Time		After Meal
888	Result		Mute
888	Record/Average display		Volume
CS	Control Solution		Insert strip
En	English		Temperature
ES	Espańol		Error
A	AM	M	Memory
P	PM		Apply Blood
24	24hr	mg/dL	Unit
	Battery		

Note: When shows up in any section of user's manual, the meter will sound and tell you the instructions.

Description of Sound

WHEN the meter will speak	WHAT the meter will say
Meter has been turned on.	Power on and greeting music.
Setting the meter.	Please set the meter. English (En) / Español (ES).
Setting Volume.	Please set the volume.
Setting Year.	Please set the year.
Setting Date.	Please set the date.
Setting Time.	Please set the time.
Meter is ready to insert test strips.	Please insert a test strip.
When the meter is ready to apply blood.	Please apply blood into the strip.
Blood Glucose test is complete and the result is shown on screen.	Blood glucose is (number) milligram per deciliter.
Humidified / Used strips.	Humidified or used strips. Please replace with a new strip.
Low Power.	Low power. Please replace with new batteries.
System error.	System error.

WHEN the meter will speak	WHAT the meter will say
Blood Glucose test result is ABOVE the measurement range of 600 mg/dL.	Unable to measure. Test result is higher than 600 milligram per deciliter. Please test again and if you get the same result, please contact your healthcare professional immediately.
Blood Glucose test result is BELOW the measurement range of 20 mg/dL.	Unable to measure. Test result is lower than 20 milligram per deciliter. Please test again and if you get the same result, please contact your healthcare professional immediately.
Press C button to delete a memory.	Please confirm the deletion.
Memory was deleted.	Memory deleted.
Memory mode.	(7/14/30/60/90) day average is (number) milligram per deciliter.
If the blood is not enough.	Insufficient blood. Please try with a new strip.
Temperature is too high and it may affect the test results.	Temperature is too high.
Temperature is too low and it may affect the test results.	Temperature is too low.
Turn off the meter.	Goodbye and power-off music.

Note: There is no speaking function for “Viewing & Deleting Test Results” in the Chapter 4.

Table of Contents

Chapter 1: Understanding Your Meter

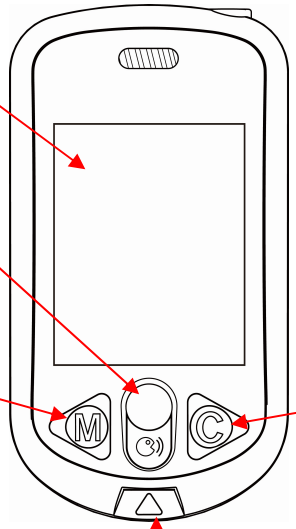
The EMV3.1 Blood Glucose Meter

Display-
Shows results, messages, and results stored in memory.

Power Button-
Press to confirm the setting.

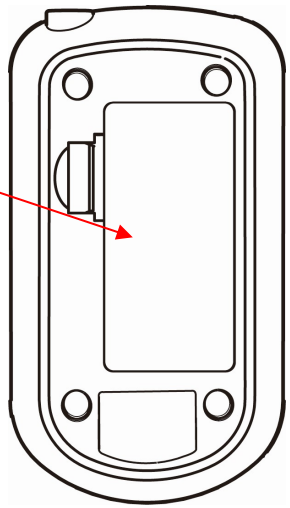
M Button-
Press to enter 7/14/30/60/90 memory, adjust setting, and scroll through results.

Test Strip Slot-
A light shows you the direction. Insert test strip here.



Battery Door-
Flip open the battery door by pushing the tab in the direction of the arrow and pulling the door up.

C Button-
Press to enter memories, adjust setting, and scroll through results.



Understanding Your Meter - the “M”, “C”, “Power” Buttons

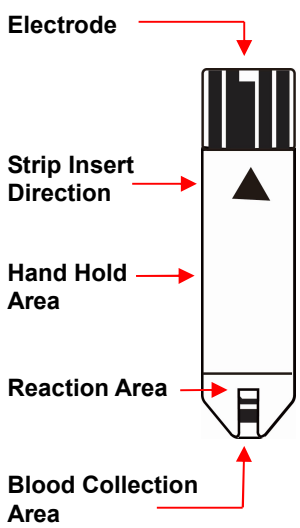
Operation and Setting	Language setting	Volume setting	Date and time setting	Mode setting 
Button	M :En C :Esp	M (Decrease) C (Increase)	M (Decrease) C (Increase)	M or C

Operation and Setting	Enter memory mode	View 7/14/30/60/90 day average	View individual result	Delete the individual result
Button	M	M	C (from last to first order)	C for 3 seconds

Operation and Setting	Turn on the meter	Turn off the meter	Confirm the setting and deletion	Speak the test result repeatedly
Button	Power	Power for 3 seconds	Power	Power

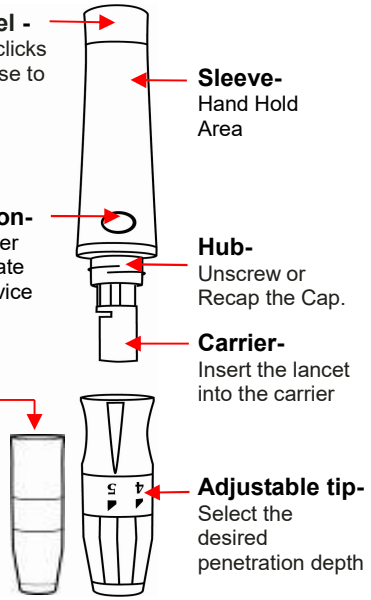
The EMV3.1 Accessories

Blood Glucose Test Strip

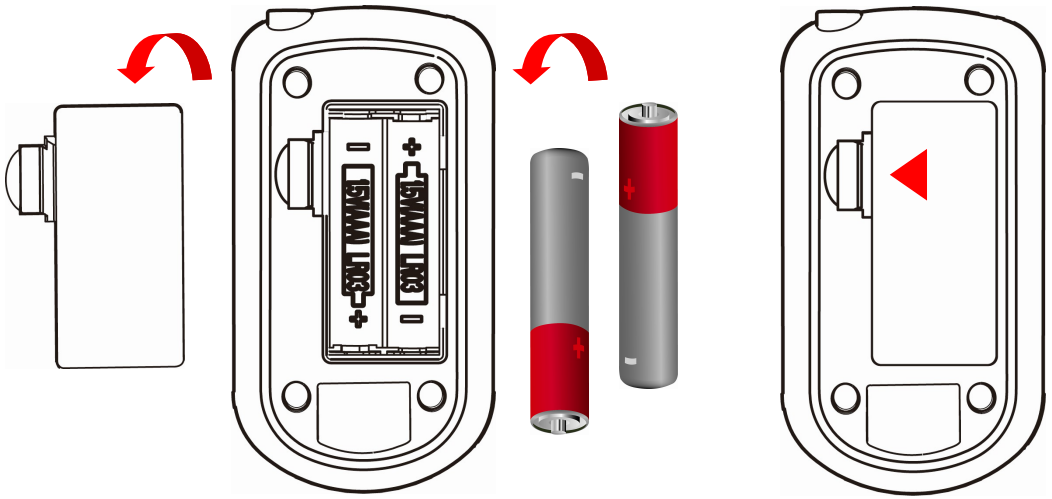


Test Strip Bottle
Control Solution Bottle

Lancing Device



Inserting Batteries

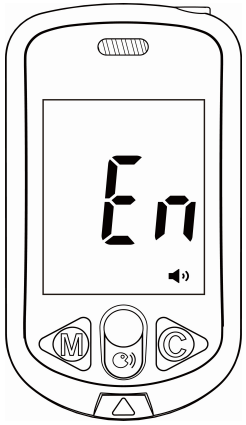


1. Open the battery door on the back of the meter by pushing the tab in the direction of the arrow and pulling the door up.

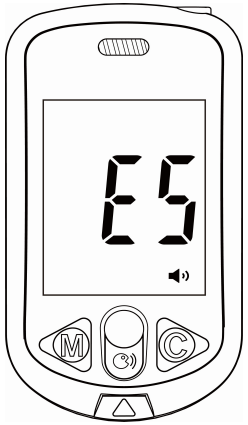
2. Insert two batteries. You will hear greeting music.

3. Put the battery door back in place and snap it closed.

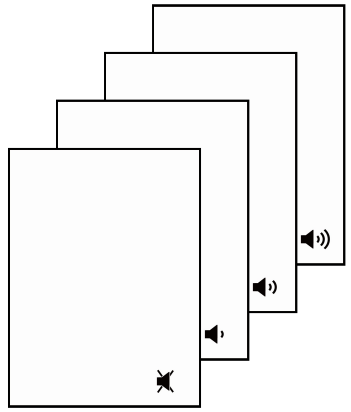
Setting The Language And Volume



1. Insert Batteries, the meter turns on. Press M button to select En or press C button to select ES. (En= English, ES = Español)



2. And press power button to confirm the setting.

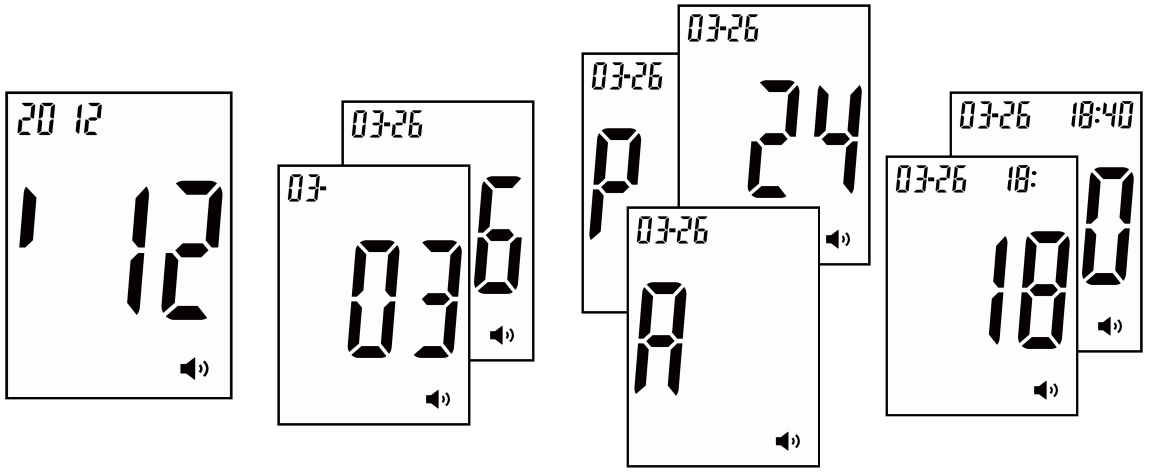


3. Repeat step 1 and 2 to set the volume.

Note:
1. **The default language of the blood glucose meter is set in English.**
2. **The unit of blood glucose meter is set at mg/dL.**
3. **Press Power Button to turn on the meter and then press C button to set the language, volume, time and date.**

Setting The Time and Date

Setting the current time and date in your meter is important if you intend to use the meter memory.



1. Press M button and C button to set the year. Press power button to confirm the setting.

2. Repeat step 1 to set the date.

3. Repeat step 1 to select P, A or 24 mode and then set the time. (P=PM, A=AM, 24=24hr mode.)

Using EMV3.1 Blood Glucose Test Strips

- Use only with **EMV3.1** Blood Glucose Meter.
- Run a control solution test every time you open a new box of test strips (See Chapter 2 "Control Solution Testing.")
- Keep the test strips in their original bottle.
- After you take a test strip out of the bottle, tightly close the bottle immediately. This keeps the test strips dry.
- Use the test strip within three minutes after taking it out of the bottle.
- The test strip is for single use only. Do not reuse it.
- Record the date you open the test strip bottle. Be sure to check the expiration date on the test strip bottle. The test strip is good for three months from the date the bottle is opened or until the expiration date on the bottle, whichever comes first.
- Store the test strip bottle and your meter in a cool dry place.
- Store the test strips between 36°F - 86°F (2°C ~30°C) and 40-85% RH. Do not freeze.
- Do not apply blood or control solution to the test strip before you insert it into the meter.
- Do not touch the test strip with wet hands. Do not bend, cut, or twist the test strips.
- **EMV3.1** Self-Monitoring Blood Glucose Test System is a “no code” system and does not require any test strip calibration.

Chapter 2: Control Solution Testing

Why Run A Control Solution Test

We recommend that you run the **EMV3.1** control solution test because it lets you know that your meter and test strips are working properly to give reliable results. You should run the control solution tests when:

- You use the **EMV3.1** Blood Glucose Meter for the first time.
- You open a new bottle of test strips.
- You think the meter or test strips may be working incorrectly.
- You drop the meter.
- You have repeated a test and the test results are still lower or higher than expected.
- You are practicing the test procedure.

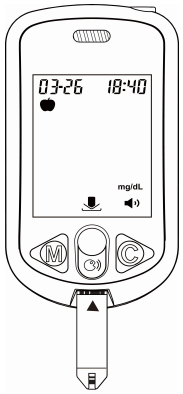
About Control Solutions

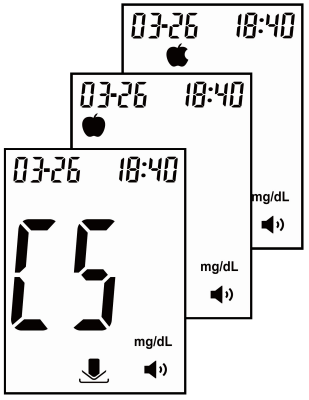
- Use only with **EMV3.1** test strips.
- Write the date you opened the control solution bottle on the bottle label. The control solutions are good for three months from the date the bottle is opened or until the expiration date on the bottle, whichever comes first.
- Do not use a control solution that is past the expiration date.
- Control solutions can stain clothing. If you spill it, wash your clothes with soap and water.
- Close the bottle tightly after every use.
- Left over control solution should not be added back into the control bottle.
- Store control solution at room temperature, between 36°F - 86°F (2°C~30°C). Do not freeze.
- If you would like to purchase **EMV3.1** Control Solutions**,** please contact your local dealer.

Running A Control Solution Test

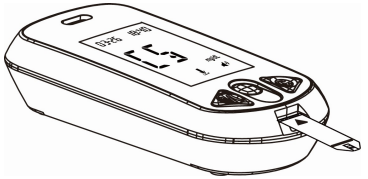
You need the meter, a test strip, and control solution.

1. Put a test strip into the meter in the direction of the arrow.





2. The meter turns on.
Press M button or C button to select CS, press power button to confirm the control solution mode. (CS means control solution mode, means before meal mode and means after meal.)

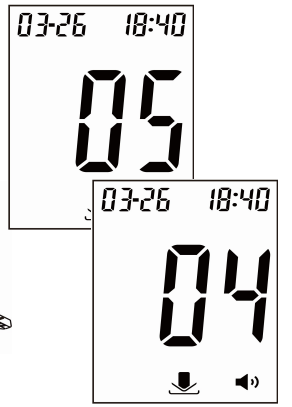


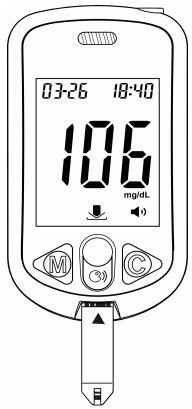
3. Place the meter on a flat surface, like a table.

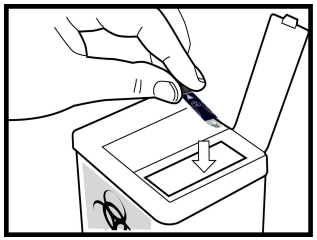
4. Remove the control solution bottle cap and wipe the tip of the bottle with a tissue.

5. Squeeze the bottle until a tiny drop forms at the tip of the bottle and place solution on top of bottle cap.

Note: Setting the meter in control solution mode will prevent the control solution reading from being added to your memory and averages.







6. Touch the drop on the bottle to cap the tip of the test strip.

7. The meter starts to count down from 5 seconds and then will display result.

8. Do not remove the test strip yet. Check if the reading falls within the range printed on the test strip bottle.

9. Press power button to repeat the test result. Or you can also press C button or M button to set the volume before repeating the result.

10. After you have compared the reading to the range printed on the test strip bottle, remove the test strip and follow your healthcare provider's recommendation for disposal of used glucose test strips to throw it away.

11. Please check if the result on the display is the same as audible result.

Note: Be aware that there are Level 2 and Level 3 ranges listed on your test strip bottle. The Level 2 and Level 3 refer to the two different control solutions that are available. Please be sure that you are looking at the correct range.

Understanding Control Solution Test Results

The label on your test strip bottle shows the acceptable ranges for the Control Solutions. The result you get should be inside the acceptable range for the appropriate control solution level. Make sure you compare the result to the correct level of control.

When the control solution result is inside the range on the test strip bottle, your test strips and your meter are working properly.

If your control solution result is not inside the acceptable range (printed on your test strip bottle), here are some things you can do to solve the problem:

Note:
If you don’t set “CS” mode, control solution values will be included in the memory and averages. Setting the meter in control solution mode will prevent the control solution reading from being added to your memory and averages.

Troubleshooting Check	*Action*
✓ Was the test strip exposed to open air for a long period of time?	If yes, repeat the control test with properly stored strips.
✓ Does test strip cap close tightly? Or was test strip cap left open?	If the cap was not tight, or the bottle was left uncapped, open a new bottle of test strips. Do not reuse the strips from the affected bottle.
✓ Is the meter functioning well?	You can use the control solutions to verify the meter's functions.
✓ Is the control solution expired or contaminated?	If yes, replace with a new control solution to check the performance of SMBG system.
✓ Were test strips and control solutions stored in cool, dry places?	If no, repeat the control test with properly stored strips or control solutions.
✓ Did you follow the testing steps properly?	If you have followed the steps properly, contact physician. If you continue to have problems please contact Customer Support at 866-994-3345.

Chapter 3: Testing Your Blood Glucose

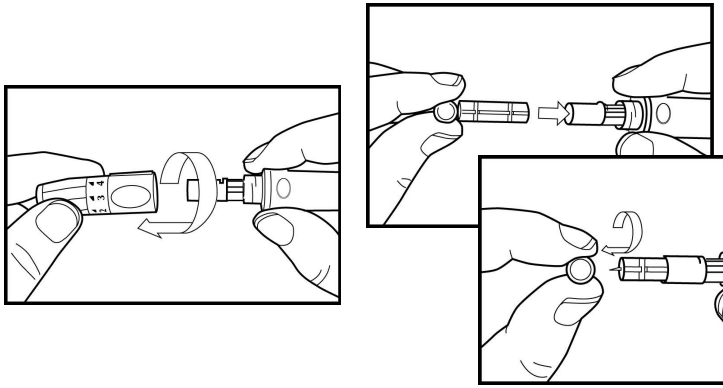
Using the Lancing Device

- The best depth setting is the lowest number that draws enough blood for a test. Try different settings to find the one that's right for you.
- Please do not share your lancing device with anyone. And always use a new, sterile lancet. Lancets are for one time use only.
- If the meter and lancing device are being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be disinfected prior to use by the second person. For the disinfection instruction, please refer to Chapter 5: Maintenance And Troubleshooting "Cleaning and disinfect your meter and supplies".

Note:
Used test strips and lancets are considered bio-hazardous waste in accordance with U.S. local regulations and should be handled as if capable of transmitting infection. The users may discuss methods for disposing used test strips and lancets with their healthcare professional.

Inserting A Lancet Into The Lancing Device

You must first load the lancet into the lancing device to get it ready for use.

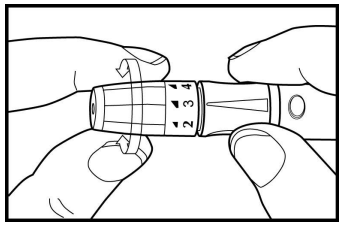


1. Unscrew the Cap.

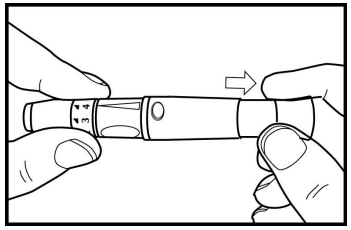
2. Insert the lancet into the lancing device firmly then twist off the protective cover.

3. Recap the front cap.

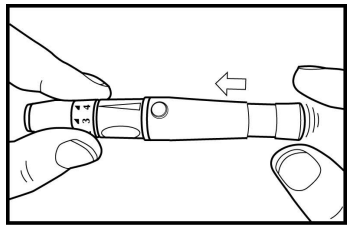
Note:
Lancets are for single use only and a new, sterile lancet should be used each time you perform a test.



4. Select the desired penetration depth.



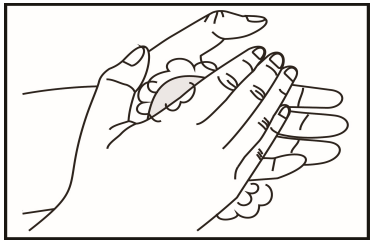
5. Pull on the sliding barrel of the lancing device until it clicks and then release.
Now the lancing device is ready.
Do not prick your finger until your meter and strip are prepared.



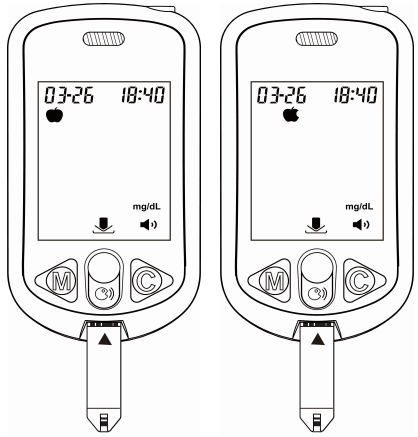
6. Set the lancing device aside until later in the test.

Note: **1. Select 1-2 for soft or thin skin, 3 for average, and 4-5 for thick or calloused skin.**
2. Lancing device and lancets are not to be shared between users. Sharing lancing devices and lancets may transmit blood borne pathogens, such as viral hepatitis.

Running A Blood Glucose Test With Blood From Your Fingertip

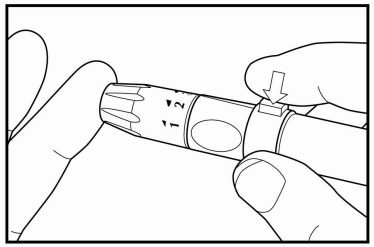


1. Wash your hands with soap and warm water. Rinse and dry thoroughly.

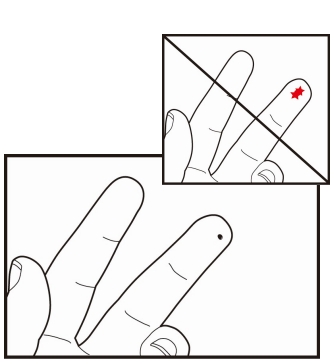


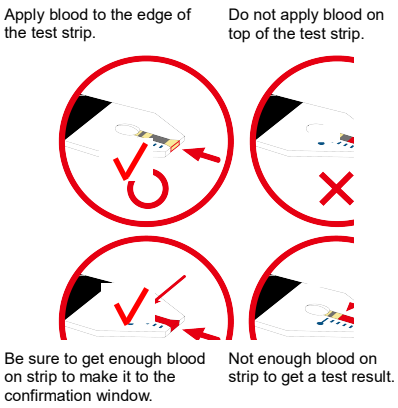
2. Put a test strip into the meter in the direction of the arrow. The meter turns on. Press M button or C button to select / mode and press power button to confirm the setting.

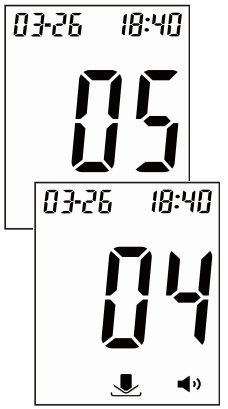
3. When the blood drop flashes on the display, the meter will speak the instructions.



4. Place the lancing device against the pad of your finger. Press the trigger button to activate the lancing device.







5. Gently squeeze and/or massage your fingertip until a round drop of blood on your fingertip.

6. Touch the blood drop at the tip of the transparent window of the test strip. Do not put blood on top of the strip. Be sure to get enough blood on the strip's reaction zone. Otherwise, an inaccurate reading may result.

7. The meter starts to count down from 5 seconds and speaks the result.

8. Press power button to repeat the test result. Or you can also press C button or M button to set the volume before repeating the result.

9. Remove the test strip and the meter turns off automatically.

Note: 1. Please make sure to apply blood when the blood drop appears on the display.
2. Please check if the result on the display is the same as audible result.

Alternative Site Testing (AST)

Understanding Alternative Site Testing

What is AST?
Besides the fingertip, you can test your palm or forearm.

What is the advantage of AST?
You have the option of testing other places on your body besides the fingertip.

Consult your healthcare professional before you begin using the palm or forearm for testing. Blood glucose test results obtained from your palm or forearm may differ significantly from fingertip samples.

We strongly recommend that you:

Do AST ONLY in the following intervals:

- In a pre-meal or fasting state (more than 2 hours since the last meal).
- Two hours or more after taking insulin.
- Two hours or more after exercise.

Do NOT use AST if:

- You think your blood glucose is low.
- You are unaware of hypoglycemia.
- Your AST results do not match the way you feel.
- You are testing for hyperglycemia.
- Your routine glucose results are often fluctuating.

Fingertip test only:

- If sick
- If blood glucose is low
- After exercising
- Two hours or less after eating
- When you have just taken insulin
- After injecting rapid-acting insulin (two hours or less)

AST Results:

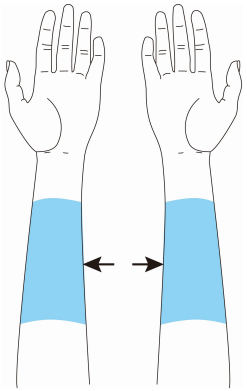
- If the blood glucose test result from the alternative site test does not match how you feel, do a fingertip test to confirm the result again.
- Do NOT change your treatment just because of an alternative site result, do a fingertip test to

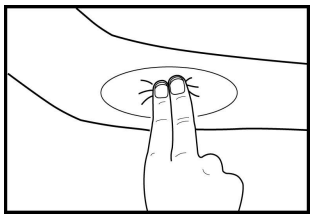
Caution:

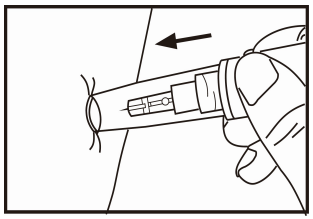
- Talk with your healthcare professional before you test palm or forearm.
- Do NOT ignore symptoms of high or low blood glucose.
- Fingertip samples are able to show the rapid change of glucose faster than forearm and palm samples.
- Measurements from alternative site testing should never be used to calibrate a continuous glucose monitor (CGM) or entered into insulin dose calculators for insulin dosing recommendations.

Running A Blood Glucose Test With Blood From Your Forearm

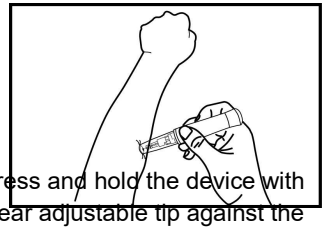
Please use the clear cap with the lancing device for AST testing



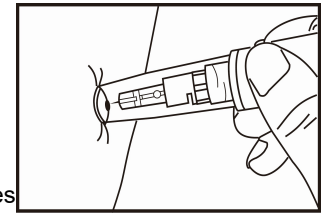




1. Massage the puncture area of forearm for a few seconds.



2. Press and hold the device with clear adjustable tip against the forearm.

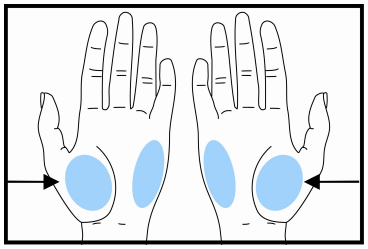


3. Press activate the lancing device. Hold the device against forearm and increase pressure until the blood sample size is sufficient.

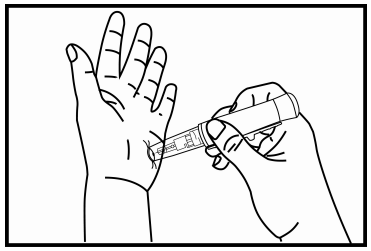
4. Wipe away the first drop with a tissue and use the second drop.

Note: 1. Check with your healthcare professional before testing sites other that the fingertip.
2. Please do NOT use the first drop of blood sample.

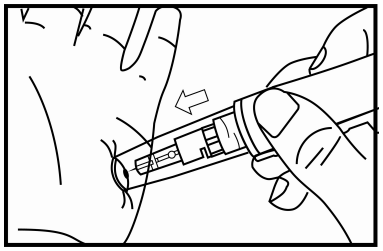
Running A Blood Glucose Test With Blood From Your Palm



1. Massage the puncture area of palm for a few seconds.



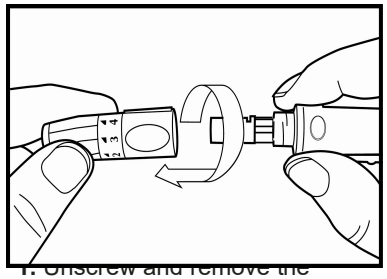
2. Press and hold the device with a clear adjustable tip against the palm.



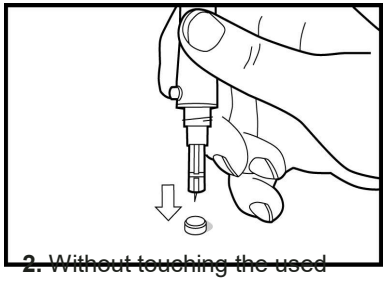
3. Press the trigger button to activate the lancing device.

4. Hold the device against palm and increase pressure until the blood sample size is sufficient.

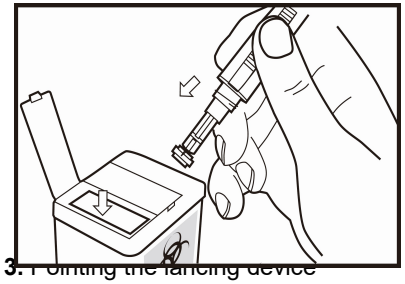
Discarding Used Lancets



1. Unscrew and remove the cap.



2. Without touching the used lancet, stick the lancet tip into its protective cover.



3. Pointing the lancing device toward a container for sharp or biohazard material, slide the ejection button down to release the covered lancet into the container.

4. After discarding, wash hands thoroughly with soap and water. Rinse and dry thoroughly.

Understanding Your Test Results

Expected Values*

The **EMV3.1** Blood Glucose test strips are plasma referenced and calibrated for easier comparison to lab results. The normal fasting blood glucose range for an adult without diabetes is 70-100 mg/dL. Two hours after meals, the blood glucose range for an adult without diabetes is less than 140 mg/dL. For people with diabetes: please consult your healthcare professional for the blood glucose range appropriate for you.

∗Reference: American Diabetes Association. Standards of medical care in diabetes. Diabetes care. 2013; Vol. 36, Suppl 1:S11-66

Unusual Test Results

If your test result does not match the way you feel, please follow these steps:

1. Run a control test, Chapter 2, "Control Solution Testing."
2. Repeat a blood glucose test, Chapter 3, "Testing Your Blood glucose."
3. If your test results still do not reflect the way you feel, call your healthcare professional immediately.

Note:

1. **Extremely high humidity may affect the test results. A relative humidity greater than 90% may cause inaccurate results.**
2. **Hematocrit below 20% may cause higher results. Hematocrit above 60% may cause lower results.**

Comparing Your Meter Result To A Lab Result

A common question is how the blood glucose results on your meter compare to the lab results. Your blood glucose can change quickly, especially after eating, taking medication, or exercising. If you test yourself in the morning, then go to the doctor's office for a blood glucose test. The results will probably not match, even if you are fasting. This is typically not a problem with your meter, it just means that time has elapsed and your blood glucose has changed.

If you want to compare your meter result to the lab result, you must be fasting. Bring your meter to the doctor's office, and test yourself by fingertip within five minutes of having blood drawn from your arm by a healthcare professional. Keep in mind that the lab could use different technology than **EMV3.1** blood glucose meter, and that blood glucose meters for self testing generally read somewhat lower or higher than the lab result.

For accuracy and precision data and for important information on limitations, see the instructions that come with your test strips.

Chapter 4: Meter Memory, Setup

Memory, Storing Test Results

Your meter stores a maximum of 480 test results with the time and date of the test. You can review them at any time. When the memory is full, the oldest result is dropped as the newest is added, so it is very important to have the correct time and date set in the meter.

Meter Setup - Using The Set Mode

By using the set mode, you can personalize your meter to suit your needs. Here are the features you can customize —

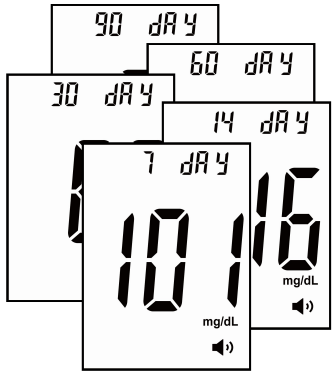
Time and Date — to set the time and date (see Chapter 1).
Language — to set the language (see Chapter 1).
Volume – to set the volume (see Chapter 1)

Note:

1. **Do not change your therapy based on one individual result in memory.**
2. **The memory is not lost when you replace the battery. You do need to check that the time and date are still correct for future readings. See Section "Setting the time and date" in Chapter 1.**
3. **Once 480 results are in memory, adding a new result causes the oldest one to be deleted.**
4. **If you don’t set “CS” mode, control solution values will be included in the memory and averages. Setting the meter in control solution mode will prevent the control solution reading from being added to your memory and averages.**

Viewing & Deleting Test Results

The meter provides 7, 14, 30, 60 and 90 days averaging to help track your blood glucose trend.



1. Press power button to turn on the meter.
2. Press M button to view averages for 7/14/30/60/90 days.

3. Press C button to view individual test result.

4. To delete a test result, press C button for more than 3 seconds and display shows "dEL". Then press power button to confirm the deletion.
5. Press C button to keep reviewing the results.
6. Press M button to go back to averages for 7/14/30/60/90 days.

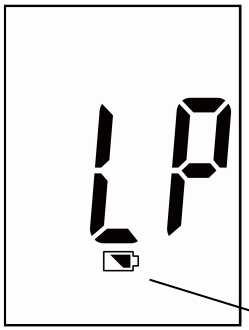
Note:

1. Press power button for 1 second and the meter will repeat the test results.

2. Press power button for 3 seconds to turn off the meter or the meter turns off automatically in 90 seconds.

Chapter 5: Maintenance and Troubleshooting

Inserting Batteries



The meter uses two alkaline 1.5V (AAA) batteries. Batteries will normally last for more than 2000 tests. Other types of 1.5V (AAA) batteries are also acceptable, but the capacity of test times may differ. Insert the batteries when you first use the meter or replace with new batteries when the "LP" (low power) message and the low battery symbol appear on the display.

The meter will not turn on the first time batteries are inserted.
Please press and hold power button or insert the test strip to turn your meter on.
The meter will turn off automatically. Or you can press and hold power button to turn your meter off.

Low battery symbol

Note:

1. **The meter won’t delete earlier records after you replace batteries.**
2. **You should reset the time and date again after you replace the batteries. See Section "Setting the Time and Date" in Chapter 1.**
3. **1.5V (AAA) x 2 batteries are available at most stores. You may take the old batteries with you for replacement.**
4. **Remove batteries when you will not be using the meter for one month or more.**

Cleaning And Disinfecting Your Meter and Lancing Device

Choosing the disinfectant

The recommended EPA-registered disinfected product is as follow:

PDI® Super SANI-CLOTH® Germicidal disposable wipe (EPA Reg. No.:9480-4)

Super Sani-Cloth germicidal wipe contains active ingredients: n-Alkyl (60% C_{14}, 30%C_{16}, 5%C_{12}, 5%C_{18}) dimethyl benzyl ammonium chlorides and n-Alkyl (68%C_{12}, 32%C_{14}) dimethyl ethylbenzyl ammonium chlorides and they have been shown to be safe for use with the **EMV3.1** meter, but any other disinfectant product with the EPA registration number may be used on this device.

Please purchase in retail stores like Walmart and Office Depot. You could also purchase on the PDI website:http://www.pdipdi.com/ or online retail sites like amazon.com, medline.com, and Expression medical supply Inc. http://www.exmed.net/.

Cleaning and Disinfection Instruction

Please keep the meter and lancing device free of dirt, dust, bloodstain, and water stains. Please follow the following guidelines to clean and disinfect your meter and lancing device.

The meter should be cleaned and disinfected at least once per week and that additional cleanings can be performed up to six times per day. Follow the cleaning instruction to prevent the growth of any microorganism and also to help improving the effectiveness of disinfection. Follow the disinfection instruction can effectively kill blood borne pathogens, such as viral hepatitis and prevent cross-contamination. If the devices are being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be disinfected prior to use by the second person.

Cleaning Instruction: All blood and other body fluids must be thoroughly cleaned from surfaces and objects before disinfection by the germicidal wipe. Open, unfold and use first germicidal wipe to remove heavy soil.

Disinfection Instruction: Unfold a clean wipe and thoroughly wet all the surface of the meter, including the strip port and other connection port. Unfold a clean wipe and thoroughly wet all the surface of the lancing device, including cap or AST cap if used. Treated area must remain visibly wet for a full 2 minutes. Let the devices air dry for 0.5 minute. Do disinfection once per week.

Do:

- Make sure the meter is turned off during cleaning and disinfection.
- Keep the test strip vials tightly closed when performing the cleaning and disinfection procedures because the fumes from the disinfectant may affect the performance of the strip
- After cleaning or disinfection, please perform the physical appearance and performance check of devices.
- Please follow the instruction on page 44 to 46.

Do Not:

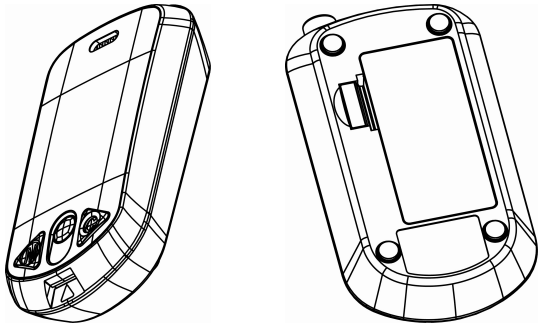
- Get any moisture in the test strip slot.
- Spray any cleaning solution directly onto the meter.
- Put the meter under water or liquid.
- Pour liquid into the meter.

Cleaning And Disinfection Frequency

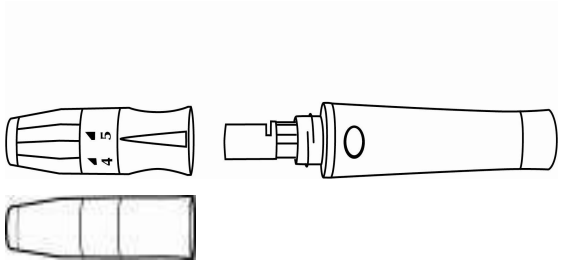
The meter device can sustain 10,000 cleaning cycles and 10,000 disinfection cycles. You can do cleaning 6 times per day and disinfecting (with a pre-clean step) once per week during the 4 year use life of the device.

4 year product life is for properly cleaning and disinfection. After 4 years, the meter must be replaced with a new meter.

Meter cleaning area



Lancing device cleaning area



Note: The entire meter and Lancing device should be cleaned and disinfected

Physical Appearance check of the meter after cleaning or disinfection

Signs of Physical Deterioration
Transparency of display
Erosion of components like strip slot.
Cracks on the case or buttons
Action:
If any signs of deterioration in physical appearance are noticed, please stop using the meter and then contact Customer Care Service toll-free at 866-994-3345 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM) for assistance.

Performance check of the meter after disinfection

Signs of malfunction
Failure to turn on the meter by pressing the “power” button or inserting the strip
Failure to store the test result in the memory mode
Reading does not fall within the control solution range when applying the level 2 control solution
Failure to turn off by pressing the “power” button for 3 seconds or removing the strip
Action:
If any signs of malfunction are noticed, please stop using the meter and then contact Customer Care Service toll-free at 866-994-3345 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM) for assistance.

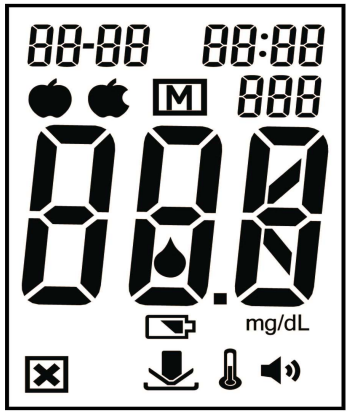
Physical Appearance check of the lancing device after cleaning or disinfection

Signs of Physical Deterioration
Erosion of components.
Cracks on the device
Action:
If any signs of deterioration in physical appearance are noticed, please stop using the meter and then contact Customer Care Service toll-free at 866-994-3345 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM) for assistance.

Performance check of the lancing device after disinfection

Signs of malfunction
Failure to screw the normal cap or AST cap on the lancing device
Failure to pull on the sliding barrel in order to click the lancing device and then release
Failure to trigger the button and then release the lancet
Action:
If any signs of malfunction are noticed, please stop using the meter and then contact Customer Care Service toll-free at 866-994-3345 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM) for assistance.

Maintenance And Testing

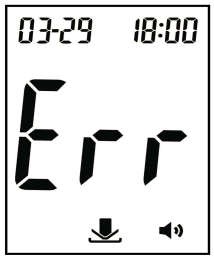
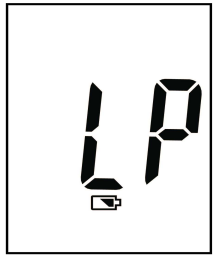


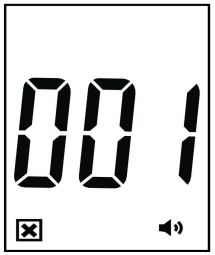
Your meter needs little or no maintenance with normal use. It automatically tests its own systems every time you turn it on and lets you know if something is wrong. (See "Screen Messages" and what to do about them.)

To make sure the display is working properly, turn off the meter. Press and hold power button to see the complete display. All the indicators should be clear and look exactly like the picture to the left. If not, please call the Customer Care Service toll-free at 866-994-3345 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM). During non-service hours, please contact your healthcare professional.

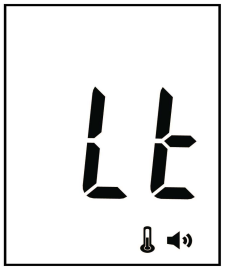
Screen Messages And Troubleshooting

Never make treatment decisions based on an error message. If you have any concerns, please contact your healthcare professional.

Message	*What it means?*	*What to do?*
	**Humidified / Used strips** The meter has detected a problem with the test strip.	**Repeat the test with a new strip.** Refer to pages 29-30 for information on sample application.
	**Low power** The meter batteries do not have enough power to perform a test.	**Replace the new batteries.**

Message	*What it means?*	*What to do?*
	**Memory fault**	**Replace the batteries first.** Refer to pages 17 and 36. If this error message appears again, please call the Customer Care Service toll-free at 866-994-3345 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM). During non-service hours, please contact your local dealer.
	**System fault** There may be a problem with the meter.	**Replace the batteries first.** Refer to pages 17 and 36. . If this error message appears again, please call the Customer Care Service toll-free at 866-994-3345 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM). During non-service hours, please contact your local dealer.

Message	*What it means?*	*What to do?*
	**Test result is higher than 600 mg/dL.**	**Re-check your glucose level.** If the result is still “HI”, try a control solution test and if the control solution test falls within the correct range, please call the Customer Care Service toll-free at 866-994-3345. (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM). During non-service hours, please contact your healthcare provider.
	**The test result is lower than 20 mg/dL.**	**Re-check your glucose level.** If the result is still “LO”, try a control solution test and if the control solution test falls within the correct range, please call the Customer Care Service toll-free at 866-994-3345. (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM). During non-service hours, please contact your healthcare provider.

Message	*What it means?*	*What to do?*
	**The “Ht” and thermometer icon appears. Temperature is too high, outside the required range of 50°F - 104°F (10°C - 40°C). This alerts users that an incorrect result may occur if the test continues.**	Relocate the meter to a location with temperature between 50°F - 104°F (10°C - 40°C).
	**The “Lt” and thermometer icon appears. Temperature is too low, outside the required range of 50°F - 104°F (10°C - 40°C). This alerts users that an incorrect result may occur if the test continues.**	Relocate the meter to a location with temperature between 50°F - 104°F (10°C - 40°C).

Chapter 6: Technical Information

Specifications

Brand name		EMV3.1 Blood Glucose Meter
Range		20~600 mg/dL
Response time		5 seconds
Memory sets		480 test results
Operating condition	Temp.	50°F -104°F (10°C-40°C)
	Relative Humidity	30-90% R.H.
Storage and transportation condition	Temp.	36°F ~86°F (2°C ~30°C)
	Relative Humidity	40-85 % R.H.
Blood sample		0.6 μL
		Fresh blood from fingertips, palm or forearm
Hematocrit (Hct)		20~60%
Power		2 Alkaline 1.5V (AAA) Batteries
Battery life		Over 2000 tests
Display dimension		1.81” x 1.30” (46.0 × 33.0 mm)
Device dimension H × W × D (mm)		3.63” x 1.96” x 0.91” (92.2 x 49.7 x 23 mm)
Weight		1.57 oz (44.6 grams) w/o batteries
Principles		Electrochemical biosensor technology

Limitations

The test strips are used for fresh capillary whole blood samples.

1. DO NOT use neonate blood sample.
2. Not to be used for diagnosis or screening of diabetes.
3. Alternative site testing with this system can be used only during steady-state blood glucose conditions.
4. Measurements from alternative site testing should never be used to calibrate a continuous glucose monitor (CGM) or entered into insulin dose calculators for insulin dosing recommendations.
5. Extreme humidity may affect the results. A relative humidity greater than 90 % may cause incorrect results.
6. The system should be used at a temperature between 50°F and 104°F (10°C and 40°C). Outside this range, the system may get incorrect results.
7. DO NOT reuse the test strips. The test strips are for single use only.
8. Hematocrit: The hematocrits between 20% and 60% will not significantly affect the results. Hematocrit below 20% may cause higher results. Hematocrit above 60% may cause lower results. If you do not know your hematocrit level, please consult with your healthcare professional.
9. Altitude up to 10,000 feet above sea level has no effect on readings.

10. The below substances up to the test concentration will not affect the test results.

Interfering substance	Concentration tested up to (mg/dL)
Gentisic Acid	6
Ascorbic Acid	4
Ibuprophen	50
Methyldopa	2
Sodium Salicylate	50
Tetracycline	1.5
Tolbutamide	100
Galactose	20
Maltose	20
Manose	10
Sucrose	50
Xylitol	200
Glipizide	8
Bilirubin	25
Cholesterol	500
Creatinine	30
Triglycerides	1000
Fructose	30

11. Interference was observed with the substances below at the concentrations listed.

Interfering substance	Interference observed at (mg/dL)
Acetaminophen	8
Dopamine	5.2
L-Dopa	4
Xylose	8
Uric Acid	15.9

Device Information

EMV3.1 SMBG System,
EMV3.1 Blood Glucose Test Strips,
EMV3.1 Blood Glucose Meter,
EMV3.1 Level 2 Control Solution,
EMV3.1 Level 3 Control Solution.

Manufacturer:
EPS BIO TECHNOLOGY CORP.
No.8, R&D RD. III, Hsinchu Science Park, Hsinchu, Taiwan 30077
TEL：+886-3-6686868 FAX：+886-3-6686866
E-mail：info@epsbio.com.tw Website：http://www.epsbio.com

Warranty

EPS warrants the original purchaser for a period of 4 years from the date of purchase. This means during the warranty period if the Self-Monitoring Blood Glucose System does not work for any reason (other than obvious abuse), EPS will replace it with a new system or an equivalent product free of charge.

Please read **EMV3.1** User's Manual before operation. If you have any questions and/or need assistance, please contact us as follows:

- Within the USA, call toll-free: 866-994-3345 (Eastern Standard Time, Mon-Fri 8:00AM~6:00PM). During non-service hours, please contact your healthcare professional.
- Outside the USA, call your authorized representative or write to:
  Customer Service E-mail: info@epsbio.com.tw

Lancing Device

Meets the requirements of MDD 93/42/EEC

Manufacturer:

STERILANCE MEDICAL (SUZHOU) INC.

68# LiTangHe RD, XiangCheng, Suzhou, China 215131
Tel: +86 512 65799308 Fax: +86 512 67217663
E-mail：guopings@xinda-medical.com

Lancet

Meets the requirements of MDD 93/42/EEC

Manufacturer:

STERILANCE MEDICAL (SUZHOU) INC.

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